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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,161	01/26/2001	Zurit Levine	802620-2005.1	8061

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,161

Applicant(s)

LEVINE ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4, 8-11, 34, and 35 and 12-16, in part, drawn to nucleic acids, classified in class 514, subclass 44.
- II. Claims 3 and 33 and 12-14, in part, drawn to polypeptides, classified in class 424, subclass 94.5.
- III. Claims 5-7 and 15 and 16, in part, drawn to antibodies, classified in class 424, subclass 139.1.
- IV. Claims 17 and 19-23, drawn to hybridization assays, classified in class 435, subclass 6.
- V. Claim 18, drawn to amplification assays, classified in class 435, subclass 6.
- VI. Claims 24-27, drawn to immuno-detection of polypeptides, classified in class 435, subclass 7.1.
- VII. Claims 28-31, drawn to nucleic acid sequence data carriers, classified in class 360.
- VIII. Claim 32, drawn to software for analyzing nucleic acid sequences, classified in class 702, subclass 20.

For each of inventions I, IV, V, VII, and VIII above, restriction to one of the following is also required under 35 USC 121: one of SEQ ID No: 1-91 or a sequence encoding one of SEQ ID No: 92-182, respectively.

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For each of inventions II, III, and VI above, restriction to one of the following is also required under 35 USC 121: one of SEQ ID No: 92-182.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention II are related to the antibodies of III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein

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can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists or antagonists of the enzyme.

The nucleic acids of Invention I are distinct from the antibodies of Invention III because they are physically and functionally distinct chemical entities.

The nucleic acid carriers of Invention VII are distinct from the products of Inventions I-III and VIII because the carriers are physically and functionally distinct chemical entities.

The software of Invention VIII is distinct from the products of Inventions I-III because the software is are physically and functionally distinct chemical entity.

The methods of Inventions IV and V are related to the DNA of Invention I as a product and process of using. However, said methods are distinct from the DNA because the DNA can also be used for recombinant production of the encoded protein.

The method of Invention VI is related to the antibodies of Invention III as a product and process of using. However, said methods are distinct from the antibodies because the antibodies can also be used as pharmaceutical compounds.

The methods of Inventions IV-VI are distinct because they comprise different steps, utilize different products and/or produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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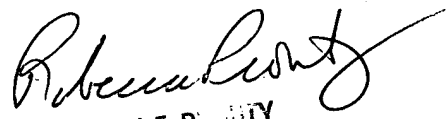
currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-6 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PROBY
PRIMARY EXAMINER
GROUP 1200
hw